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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JALLA, SANJOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,801	BRENNAN ET AL.	
	Examiner	Art Unit	
	Sanjoo Shree Jalla	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-125* is/are pending in the application.

4a) Of the above claim(s) *56-63,67,71-114,119,124 and 125* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-66,68-70,115-118 and 120-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 12/17/02, is acknowledged.

   Claims 1-55 have been cancelled
   Claims 115-125 have been added
   Claims 56-125 are pending

2. Applicant's election with traverse of group III, (claims 64-66, 68-71 and 75-81), drawn to a method of identifying a compound comprising pre-incubating T_{ck} cells and T_{ter} cells with a compound to be tested, and of species TNFα, in response to the restriction requirement filed on 12/19/05 is acknowledged. The traversal is on the grounds that that the antibodies of Group VIII are simply a subset of the compounds of Group III and that Groups III and VIII are so closely related that they should be considered together in this application. Further, applicant's traversal for species election is on the grounds that the three species (TNF-α, NFK-β and PI3K) are related as a part of the same biochemical pathway hence related as three different ways of measuring the same biochemical effect. This is not found to be persuasive because Group III and VIII are patentably distinct methods. Group III method involves identifying a compound with efficacy in the treatment of a disease whereas, Group VIII method involves merely identifying an antibody-like molecule.

   The requirement is still deemed proper and is therefore made FINAL.

   Claims 64-66, 68-70, 115-118 and 120-123 read on the elected invention and are being acted upon.

   Claims 56-63, 67, 72-74, 82-114 and 119 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non elected invention.

   Claims 71, 75-81 and 124-125 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non elected species.

3. The abstract of the disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP § 608.01(b).

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. However, the use of trademarks has been noted in this application (e.g. VLSIPS™ on page 307). Trademarks should be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any number,

which might adversely affect their validity as trademarks.

5. Claims 66 and 68 are objected to because of the following informalities: The word "tumor necrosis factor-A" in claims 66 and 68 reads as "tumor necrosis factor - (upside down) A". Also, T_{ck} in claims 115-117 and 120-123 reads as Tck. Appropriate correction in spelling is required.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

Claims 64-66, 68-70, 115-118 and 120-123 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

It is unclear how the compound is identified for its ability to selectively inhibit T_{ck} cells. The claims are incomplete for omitting essential steps. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The preamble recites a method of identifying a compound with efficacy in the treatment of a chronic inflammatory disease whereas the method concludes with testing the compound for an ability to selectively inhibit T_{ck} cells. The method steps do not show (i) how inhibition of T_{ck} cells is measured or what inhibition of T_{ck} indicates, (ii) use of monocytes in the method and (iii) fixation step in the method.

7. Claims 64-66, 68-70, 115-118 and 120-123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

   A) Claims 64-66, 68-70, 115-118 and 120-123 are indefinite and ambiguous in the recitation of the abbreviation "T_{ck} cells" and "T_{tcr} cells" rather than "cytokine stimulated T cells" and T-cell receptor stimulated T cells respectively, because an abbreviation can indicate a number of entities. Applicant should amend the claims to recite the proper name of the claimed cells.

   B) B. Claim 116 is indefinite in the recitation of "antibody-like molecule", because it is unclear what "antibody-like molecule" essentially refers to. Specification defines ""antibody-like molecule" to include "whole antibodies having specificity for T_{ck} cells and fragments of such antibodies which retain a specificity for T_{ck} cells" (page 21 and 22 of instant specification). "Include" is not limited to the recited definition therefore "antibody-like molecule" could include T-cell receptor or any other molecule that has "antibody-like" characteristics. As "antibody-like" characteristics

are not defined, one of ordinary skill in the art would not be reasonably able to establish the metes and bounds of the claimed invention.

C) Claim 68 is indefinite and ambiguous in the recitation of "T_{ck} cells" or "T_{tcr} cells", because it is unclear how in a method step, two cell types in step (i) and (ii) of the method become one cell type in step (iii) of the method i.e. in step (i) and (ii) of the method both T_{ck} cells and T_{tcr} cells are required whereas in step (iii) either T_{ck} cells or T_{tcr} cells are required. One of ordinary skill in the art would not be reasonably able to establish the metes and bounds of the claimed invention.

D) Claim 68 is indefinite and ambiguous in the recitation of "resuspending said T_{ck} cells and T_{tcr} cells", because it is unclear how the T_{ck} cells that are already in culture, in step (i) of the method are put in culture again in step (ii) of the method. One of ordinary skill in the art would not be reasonably able to establish the metes and bounds of the claimed invention.

E) Claim 68 is indefinite and ambiguous in the recitation of "fixation", because it is unclear what is the "fixation" of. Something appears to be "fixed" in the claims but there is no recitation of precisely what and precisely when. One of ordinary skill in the art would not be reasonably able to establish the metes and bounds of the claimed invention.

F) Claim 122 is indefinite and ambiguous in the recitation of "pre-inflammatory", because it is unclear what pre-inflammatory cytokines refers to. It is a vague term making interpretation of the claim ambiguous and unclear. One of ordinary skill in the art would not be reasonably able to establish the metes and bounds of the claimed invention.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this office action:

A person shall be entitles to a patent unless-

> *(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

Claims 64-66, 68-70, 115, 117-118 and 120-123 are rejected under 35 U.S.C. 102 (b) as being anticipated by Parry et.al. (The Journal of Immunology. 1997; 158: 3673-3681).

Parry et.al. teach a method of identifying a compound that can be used for the treatment of rheumatoid arthritis (RA) (i.e. chronic inflammatory disease) (see in particular, page 3673, right hand column, 1st paragraph), comprising testing IL-2 (i.e. the compound) for its ability to inhibit monocyte production of TNF-α (see in particular page 3674, right hand column, section "T cell line preparation") (i.e. inhibition of T_{ck} cell induced release

of pro-inflammatory cytokine from monocytes). Parry et.al. further teach that T-cells were cultured in the presence of cytokine IL-2 (i.e. to produce T_{ck} cells). Further, cytokine stimulated T cells were incubated with IL-2 (i.e. the compound) (see in particular page 3674, right hand column, section "T cell line preparation"). Subsequently, T cells were incubated with monocytes and the amount of TNFα released by the cells was assayed (see in particular pages 3674 and 3675, under the section "T lymphocyte stimulation and fixation" and "Monocyte culture"). Further, TNFα production was measured (i.e. assayed) by ELISA (see in particular page 3675, left hand column, section "Measurement of cytokines"). Additionally, Parry et.al. teach use of IL-10 mAb to test the ability of the antibody to inhibit T_{ck} cells to induce proinflammatory cytokine release from a monocyte (see in particular page 3678, Fig 6). Parry et.al. further teach preparation of T cell lines from synovial membrane samples of RA patients (i.e. isolation of T_{ck} cells from synovial tissue) (see in particular page 3674, right hand column, section "T cell line preparation").

Further, Parry et.al. teach a method of identifying a compound that can be used for the treatment of rheumatoid arthritis (i.e. chronic inflammatory disease) (see in particular page 3673, right hand column, 1st paragraph, last 2 lines), comprising incubating T cells stimulated with anti-CD3 mAb OKT3 (i.e. T_{tcr} cells) with anti- TNFα mAb (i.e. a compound), followed by washing (i.e. resuspending) step in the absence of the compound. T_{tcr} cells were incubated with monocytes and the amount of TNFα released by the cells was assayed (see in particular pages 3674 and 3675, under the section "T lymphocyte stimulation and fixation" and "Monocyte culture").

The reference clearly anticipates the invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 115-116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et.al. (The Journal of Immunology. 1997; 158: 3673-3681), in view of Sebbag et.al. (Eur. J. Immunol. 1997; 27: 624-632).

The teachings of Parry et.al. have been discussed previously.

Parry et.al. do not teach the compound to be identified for efficacy in the treatment of chronic inflammatory disease to be an antibody (claim 116).

Sebbag et.al. teach use of IL-10 mAb (i.e. the compound) to test the ability of the antibody to inhibit T_{ck} cells to induce proinflammatory cytokine release from monocyte (see page 629, Fig 6 in particular).
Given that the IL-10 mAb has inhibitory effect on T_{ck} cells to induce proinflammatory cytokine release from monocyte, it would have been obvious to one of ordinary skill in the art at the time the invention was made to identify the effect of IL-10 mAb (i.e. the compound) efficacy in the treatment of chronic inflammatory disease as taught by Sebbag et.al.

The ordinary artisan at the time the invention was made would have been motivated to identify IL-10 mAb (i.e. the compound) as taught by Sebbag et.al. because IL-10 mAb has the ability to inhibit T_{ck} cells to induce proinflammatory cytokine release from monocyte (see page 629, Fig 6 in particular).

From the teachings of the references, it was apparent that one of ordinary skill in the art would have a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanjoo Jalla whose telephone number is (571) 272-4453. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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2/21/06
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